July 11, 2006

Elmer Rauckman, Ph.D., DABT
Toxicology and Regulatory Affairs
Solutia Corporation
1201 Anise Court
Freeburg, IL 62243

Dear Dr. Rauckman:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for BQAOH/BQAES Pair, posted on the ChemRTK HPV Challenge Program Web site on February 23, 2005. I commend Solutia Corporation for its commitment to the HPV Challenge Program.

EPA reviews test plans and robust summaries to determine whether the reported data and test plans will provide the data necessary to adequately characterize each SIDS endpoint. On its Challenge Web site, EPA has provided guidance for determining the adequacy of data and preparing test plans used to prioritize chemicals for further work.

EPA will post this letter and the enclosed comments on the HPV Challenge Web site within the next few days. As noted in the comments, we ask that Solutia advise the Agency, within 60 days of this posting on the Web site, of any modifications to its submission. Please send any electronic revisions or comments to the following e-mail addresses: oppt.ncic@epa.gov and chem.rtk@epa.gov.

If you have any questions about this response, please contact Mark Townsend, Chief of the HPV Chemicals Branch, at 202-564-8617. Submit questions about the HPV Challenge Program through the "Contact Us" link on the HPV Challenge Program Web site pages or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached by e-mail at tsca-hotline@epa.gov.

I thank you for your submission and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

/s/

Oscar Hernandez, Director
Risk Assessment Division

Enclosure

cc: W. Penberthy
J. Willis

EPA Comments on Chemical RTK HPV Challenge Submission:
1,6-Bis(dibutylethylammonium)hexane hydroxide (BQAOH) and
1,6-Bis(dibutylethylammonium)hexane ethylsulfate (BQAES)

Summary of EPA Comments

The sponsor, Solutia Inc., submitted a test plan and robust summaries to EPA for 1,6-Bis(dibutylethyl-ammonium)hexane hydroxide (BQAOH, CAS No. 111960-92-0) and 1,6-Bis(dibutylethylammonium)-hexane ethylsulfate (BQAES, CAS No. 68052-49-3) dated January 10, 2005. EPA posted the submission on the ChemRTK HPV Challenge Web site on February 23, 2005.

EPA has reviewed this submission and has reached the following conclusions:

1. Analog Justification. EPA does not consider didecyldimethylammonium chloride (DDDMAC; CAS No. 7173-51-5) a suitable analog for the sponsored substances.

2. Physicochemical Properties. The submitted data for these endpoints are adequate for the purposes of the HPV Challenge Program.

3. Environmental Fate. EPA agrees with the submitter's plan to test for the biodegradation endpoint.

4. Health Effects. Acute toxicity data are adequate for the purposes of the HPV Challenge Program. The submitter needs to provide data for the remaining SIDS endpoints.

5. Ecological Effects. EPA agrees with the submitter's proposal to test all ecological endpoints according to OECD guidelines.

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.

EPA Comments on the 1,6-bis(dibutylethylammonium)Hexane Hydroxide (BQAOH) and 1,6-bis(dibutylethylammonium)hexane Ethylsulfate (BQAES) Challenge Submission

Analog Justification

EPA disagrees that DDDMAC is an appropriate analog for the sponsored substances. DDDMAC is a mono quaternary alkylammonium compound. The sponsored substances, BQAOH and BQAES, carry two such quaternary alkylammonium groups, and the toxicological effects of having two such groups are unknown. The EPA PR Notice 88-2 (FEB 26, 1988) cited in the Test Plan as guidance for clustering the quaternary ammonium compounds for testing addresses only monofunctional quats.

Test Plan

Physicochemical Properties (melting point, boiling point, vapor pressure, water solubility, and partition coefficient)

The submitted data for these endpoints are adequate for the purposes of the HPV Challenge Program.

Environmental Fate (photodegradation, stability in water, biodegradation, fugacity)

The submitted data for photodegradation, stability in water and fugacity are adequate for the purposes of the HPV Challenge Program.

Biodegradation. EPA agrees with the submitter's plan to test for biodegradation and suggests that the submitter conduct the ready biodegradation test according to OECD TG 301 rather than TG 302.

Health Effects (acute toxicity, repeated-dose toxicity, genetic toxicity, and reproductive/developmental toxicity)

EPA agrees with the submitter that the acute toxicity endpoint has been addressed for the purposes of the HPV Challenge Program. However, EPA disagrees that the remaining endpoints have been addressed by the submitted data for the proposed analog, DDDMAC (see above under Analog Justification). If data on a more suitable analog are not available, the submitter needs to provide data for the genetic, repeated-dose, reproduction, and developmental toxicity endpoints on one of the subject chemicals according to OECD TGs 471 (gene mutations), 473 (chromosomal aberrations) and 422 (combined screening test for repeated-dose/reproductive/developmental toxicity), respectively.

Ecological Effects (fish, invertebrates, and algae)

EPA agrees with the submitter's proposal to test all ecological endpoints in accordance with OECD TGs 201, 202, and 203 for aquatic plant, aquatic invertebrate, and fish, respectively.

Followup Activity

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.